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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/164,714	10/01/98	TUCKER K	7116-074

HM22/0229

PENNIE AND EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK NY 10036

EXAMINER	
WILSON, M	
ART UNIT	**PAPER NUMBER**
1633	3

DATE MAILED: 02/29/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/164,714	Tucker et al.
Examiner	**Group Art Unit**
Wilson, Michael C.	1633

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-70* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-70* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Notice to Comply with Sequence Rules

☒ Seq. Error Report

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, 18 and 19, drawn to an OMP21 protein, classified in class 530, subclass 395.

II. Claims 9-17, 20 and 21, drawn to nucleic acids, vectors and host cells comprising vectors, classified in class 435, subclass 325.

III. Claims 22-25, drawn to bacteria with a deletion in the OMP21 gene, classified in class 435, subclass 252.3.

IV. Claims 26-53, 67, 68, 69 and 70, drawn to pharmaceutical compositions, a method of raising an immune response and methods of treatment using such compositions, classified in various classes and subclasses.

V. Claim 54, drawn to anti-sera, classified in class 424, subclass 130.1.

VI. Claim 55-58, drawn to antibodies, classified in class 530, subclass 387.1.

VII. Claims 59-61, drawn to methods of detecting antibodies using various compositions, classified in various classes and subclasses.

VIII. Claims 62-64, drawn to methods of detecting proteins using various compositions, classified in various classes and subclasses.

IX. Claims 65 and 66, drawn to a method of detecting nucleic acids using nucleic acids, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Groups I and II are unrelated because the protein can be used to isolate antibodies while nucleic acids, vectors and host cells comprising vectors can be used to make protein. The protocols and reagents required to use proteins are materially distinct and separate than those required to use nucleic acids. The protein is not required for the nucleic acid and the nucleic acid is not required for the protein.

Groups I and III are unrelated because the protein can be used to isolate antibodies while the bacteria with a deletion in the OMP21 gene can be used for transformation. The protocols and reagents required to use proteins are materially distinct and separate than those required to use nucleic acids. The protein is not required for the bacteria with the deletion and the bacteria with the deletion does not require the protein.

Groups I and IV are unrelated because the protein can be used to isolate antibodies while the pharmaceutical compositions which are not proteins can be used to express proteins *in vivo* and because the pharmaceutical composition which is a protein may be used to treat disease. The protein used to isolate antibodies is not disclosed as being used to treat disease and the protein used to treat disease is not disclosed as being used to isolate antibodies. The protocols and reagents required to use nucleic acids is materially distinct and separate than those required for protein. The pharmaceutical nucleic acids are not required for the protein and the protein is not required for the pharmaceutical nucleic acids.

Groups I and V are unrelated because the proteins can be used to detect proteins (group 62-64) while the anti-sera can be used to treat patients. The proteins and the anti-sera are not disclosed as being used together. The protocols and reagents used to work with proteins are materially distinct and separate than those required for anti-sera.

Groups I and VI are unrelated because the proteins can be used to elicit an immune response *in vivo* while the antibody can be used to detect protein. The protein and the antibodies have different modes of action because the protein elicits antibodies and the antibodies are used to recognize proteins. The protein is not required to use the antibody and the antibody is not required to use the protein.

Groups I and VII, VIII or IX are patentably distinct because the proteins can be used to elicit an immune response *in vivo* while the method of contacting a sample with a pharmaceutical composition can be used to detect antibodies or proteins. The protein can be used for other methods such as inducing an immune response and the methods can be performed with nucleic acids instead of proteins. The protocols and reagents required to use proteins are materially distinct and separate than those required to used nucleic acids to detect antibodies, proteins or nucleic acids. Therefore, the inventions are patentably distinct.

Groups II and III are unrelated because the nucleic acids, vectors and host cells comprising vectors can be used to make protein while the bacteria with a deletion in the OMP21 gene can be used to isolate bacterial proteins that are not OMP21. The nucleic acids, vectors and

host cells comprising vectors do not require the bacteria and the bacteria do not require the nucleic acids, vectors and host cells comprising vectors.

Groups II and IV are unrelated because the nucleic acids, vectors and host cells comprising vectors can be used to make protein *in vitro* while the pharmaceutical compositions can be used to treat patients *in vivo*. The protocols and reagents required for nucleic acids, vectors and host cells *in vitro* are materially distinct and separate than those required to treat patients using nucleic acids, vectors or proteins. The pharmaceutical compositions require the consideration of a therapeutic effect which is not required for the nucleic acids, vectors and host cells. The nucleic acids, vectors and host cells comprising vectors do not require the pharmaceutical composition and the pharmaceutical composition does not require the nucleic acids, vectors and host cells.

Groups II and V or VI are patentably distinct because the nucleic acids, vectors and host cells comprising vectors can be used to make protein while the anti-sera and antibodies can be used to isolate protein. The protocols and reagents required to use nucleic acids, vectors and host cells comprising vectors are materially distinct and separate than those required to use anti-sera or antibodies. The nucleic acids, vectors and host cells comprising vectors do not require the anti-sera or antibodies and anti-sera or antibodies do not require the nucleic acids, vectors and host cells comprising vectors.

Groups II and VII, VIII or IX are patentably distinct because the nucleic acids, vectors and host cells comprising vectors can be used to make protein while the method of contacting a

sample with a pharmaceutical composition can be used to detect proteins, antibodies or nucleic acids. The nucleic acids, vectors and host cells can be used for a materially different purposes, i.e. making protein or using *in vivo*. The method can be performed with various reagents such as proteins and antibodies. The protocols and reagents required to use proteins are materially distinct and separate than those required to used nucleic acids to detect antibodies, proteins or nucleic acids. Therefore, the inventions are patentably distinct.

Groups III and IV are unrelated because the bacteria with a deletion in the OMP21 gene can be used for transformations while the pharmaceutical compositions can be used to treat patients. The protocols and reagents required to use bacteria are materially distinct and separate than those required to use pharmaceutical compositions *in vivo*. The bacteria is not used as a pharmaceutical composition and the pharmaceutical composition is not used with the bacteria.

Groups III and V or VI are unrelated because the bacteria with a deletion in the OMP21 gene can be used for transformations while the anti-sera and antibodies can be used to detect protein. The protocols and reagents required for bacteria are materially distinct and separate than those required to use anti-sera or antibodies. The bacteria do not require the anti-sera or antibodies and anti-sera or antibodies do not require the bacteria.

Groups III and VII, VIII or IX are patentably distinct because the bacteria with a deletion in the OMP21 gene can be used for transformations while the method of contacting a sample with a pharmaceutical composition can be used to detect proteins, antibodies or nucleic acids. The bacteria is not required for the pharmaceutical compositions and the pharmaceutical compositions

are not required for the bacteria. The protocols and reagents required to use bacteria are materially distinct and separate than those required to detect proteins, antibodies or nucleic acids.

Groups IV and V or VI are unrelated because the pharmaceutical compositions can be used to treat patients while the anti-sera and antibodies can be used to isolate proteins. The protocols and reagents required to use pharmaceutical compositions are materially distinct and separate than those required to use anti-sera or antibodies. The pharmaceutical compositions are not required for the anti-sera and antibodies and the anti-sera and antibodies are not required for the pharmaceutical compositions.

Groups IV and VII, VIII or IX are patentably distinct because the pharmaceutical compositions can be used to treat patients while the method of contacting a sample with a pharmaceutical composition can be used to detect proteins, antibodies or nucleic acids. The pharmaceutic compositions require the consideration of a therapeutic effect which is not required for the methods. The pharmaceutical compositions can be used to detect proteins, antibodies or nucleic acids or to treat patients. The protocols and reagents required to use pharmaceutical compositions *in vivo* are materially distinct and separate than those required to detect antibodies, proteins or nucleic acids. Therefore, the inventions are patentably distinct.

Groups V and VI are unrelated because the anti-sera can be used to treat patients in need of serum while the antibodies can be used to detect proteins. The use of anti-sera *in vivo* requires separate considerations than the mere antibody which does not require *in vivo* considerations. The anti-sera is not required for the antibody and the antibody does not require the anti-sera.

Groups V or VI and VII, VIII or IX are patentably distinct because the anti-sera and antibodies can be used to isolate proteins while the method of contacting a sample with a pharmaceutical composition can be used to detect proteins, antibodies or nucleic acids. The anti-sera requires the consideration of *in vivo* use which is not required for the methods. The methods claimed do not require the anti-sera or antibody because they can be performed using proteins or nucleic acids. The anti-sera and antibodies can be used to treat patients which is materially distinct and separate than detecting antibodies, proteins or nucleic acids. Therefore, the inventions are patentably distinct.

Groups VII and VIII are patentably distinct because the method of detecting immunocomplexes using antibodies and proteins require materially distinct and separate protocols. The method of detecting antibodies can be used to detect an immune response while the method of detecting protein can be used to detect the presence of a microorganism. The method of detecting antibodies is not required for the method of detecting protein and the method of detecting protein is not required for the method of detecting antibodies. Therefore, the inventions are patentably distinct.

Groups VII and IX are patentably distinct because the method of detecting antibodies and nucleic acids require materially distinct and separate protocols. The method of detecting antibodies can be used to detect an immune response while the method of detecting nucleic acids can be used to detect the protein expression. The method of detecting antibodies is not required

for the method of detecting nucleic acids and the method of detecting nucleic acids is not required for the method of detecting antibodies. Therefore, the inventions are patentably distinct.

Groups VIII and IX are patentably distinct because the method of detecting proteins and nucleic acids require materially distinct and separate protocols. The method of detecting proteins require proteins or antibodies while the method of detecting nucleic acids requires probes. The method of detecting proteins is not required for the method of detecting nucleic acids and the method of detecting nucleic acids is not required for the method of detecting antibodies. Therefore, the inventions are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for one Group is not required for any of the other Groups, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

2. This application contains claims directed to the following patentably distinct species of the claimed invention: pharmaceutical compositions which are nucleic acids, proteins or transformed cells.

Nucleic acids, proteins and transformed cells are patentably distinct pharmaceutical compositions because the nucleic acids can be used as probes while the proteins can be used to isolate antibodies and the transformed cells can be used to isolate proteins other than OMP21. The protocols and reagents required to use nucleic acids, proteins and transformed cells are materially distinct and separate. The nucleic acids, proteins and transformed cells are not disclosed as being used together. Therefore, the species are patentably distinct. If applicants elect Group IV, VII or VIII, applicants should elect one of the claimed species of pharmaceutical compositions.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 26-53, 59-64 and 67-70 are generic.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Sequence Listing

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. **The use of N's is not permitted.** Applicants must file a "Sequence Listing" accompanied by directions to enter the listing into the specification as an amendment. Applicant also must provide statements regarding sameness and new matter with regards to the CRF and the "Sequence Listing." Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson whose telephone number is (703) 305-0120. The examiner can normally be reached on Monday through Friday from 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. The fax phone number for this Group is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 305-0196.

Michael C. Wilson

JOHN L. LeGUYADER
PRIMARY EXAMINER
GROUP 1800
1600

Application No.: 09/164714

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- [ ] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- [ ] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [ ] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [X] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [ ] 7. Other: _____

Applicant Must Provide:

- [X] An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- [X] An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- [X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
For PatentIn software help, call (703) 308-6856

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE